DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Pinnacle Spine Group
% Meredith May, MS, RAC
Empirical Consulting, LLC
4628 Northpark Drive
Colorado Springs, Colorado 80918

December 2, 2014

Re: K141282
Trade/Device Name: PSG 5.5mm Cannulated Pedicle Screw System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNH, MNI
Dated: October 28, 2014
Received: October 31, 2014

Dear Ms. May:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K141282

Device Name
PSG 5.5mm Cannulated Pedicle Screw System

Indications for Use *(Describe)*

The PSG 5.5mm Cannulated Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformity, or curvature (i.e., scoliosis, kyphosis, and lordosis), tumor, stenosis, pseudoarthrosis, and previous failed fusion.

The PSG 5.5mm Cannulated Pedicle Screw System is a non-cervical spinal fixation system. Pedicle screw fixation is limited to skeletally mature patients.

Type of Use (Select one or both, as applicable)
☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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5. 510(K) SUMMARY

Submitter's Name:	Pinnacle Spine Group
Submitter's Address:	1601 Elm Street, Suite 1930 Dallas, TX 75201
Submitter's Telephone:	214.466.1428
Contact Person:	Meredith L. May, MS Empirical Testing Corp. 719.337.7579
Date Summary was Prepared:	9 May 2014
Trade or Proprietary Name:	PSG 5.5mm Cannulated Pedicle Screw System
Common or Usual Name:	Orthosis, Spinal Pedicle Fixation Orthosis, Spondylolisthesis Spinal Fixation Orthosis, Spinal Pedicle Fixation, For Degenerative Disc Disease
Classification:	Class III per 21 CFR §888.3070
Product Code:	NKB, MNI, MNH
Classification Panel:	87 Orthopedic

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The PSG 5.5mm Cannulated Pedicle Screw System is a multiple component, posterior spinal fixation system which consists of pedicle screws, rods, cross-connectors, and locking cap set screws. All of the components are available in a variety of sizes to match more closely to the patient's anatomy. All components are made from titanium alloy described by such standards as ASTM F136.

INDICATIONS FOR USE

The PSG 5.5 mm Cannulated Pedicle Screw System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformity, or curvature (i.e., scoliosis, kyphosis, and lordosis), tumor, stenosis, pseudoarthrosis, and previous failed fusion.

The PSG 5.5mm Cannulated Pedicle Screw System is a non-cervical spinal fixation system. Pedicle screw fixation is limited to skeletally mature patients.

The indications for use for the PSG 5.5mm Cannulated Pedicle Screw System is similar to that of the predicate devices listed in Table 5-1.

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TECHNOLOGICAL CHARACTERISTICS

The intended use and technological features of the PSG 5.5mm Cannulated Pedicle Screw System do not substantially differ from the legally marketed predicate devices. The predicate devices and the PSG 5.5mm Cannulated Pedicle Screw System are designed for posterior stabilization to provide immobilization and stabilization of spinal segments as an adjunct to fusion.

Table 5-1 Predicate Devices

510k Number	**Trade or Proprietary or Model Name**	**Manufacturer**
K000236	Synergy VLS Open	Interpore
K103490, K033901, K955348	Moss Miami Titanium	DePuy Spine Inc.
K081080 (Primary Predicate)	TSRH	Medtronic
K020279, K051971, K024096	OPTIMA™	U&I Corporation
K102870	Spine Proliant Screw System	Exactech

PERFORMANCE DATA

The PSG 5.5mm Cannulated Pedicle Screw System has been tested in the following test modes:

- Static axial compression bending per ASTM F1717-13
- Static torsion per ASTM F1717-13
- Dynamic axial compression bending fatigue per ASTM F1717-13

The results of this non-clinical testing show that the strength of the PSG 5.5mm Cannulated Pedicle Screw System is sufficient for its intended use and is substantially equivalent to legally marketed predicate devices.

CONCLUSION

The overall technology characteristics and mechanical performance data lead to the conclusion that the PSG 5.5mm Cannulated Pedicle Screw System is substantially equivalent to the predicate device.